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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,653	09/03/2003	Daniel J. Cook	14/1454US	8300
22822	7590	11/01/2006	EXAMINER	
LEWIS, RICE & FINGERSH, LC ATTN: BOX IP DEPT. 500 NORTH BROADWAY SUITE 2000 ST LOUIS, MO 63102			EREZO, DARWIN P	
			ART UNIT	PAPER NUMBER
			3731	
DATE MAILED: 11/01/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/656,653	Applicant(s) COOK, DANIEL J.	
	Examiner Darwin P. Erez	Art Unit 3731	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/3/03;9/23/04</u> . | 6) <input type="checkbox"/> Other: <u>IDS: 1/26/05</u> .                               |

## DETAILED ACTION

### *Information Disclosure Statement*

1. The information disclosure statements (IDS) submitted on 9/3/03, 9/23/04 and 1/26/05 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-26, 28-33 and 45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 1 recites the limitation "the posterior base" in lines 8-9. There is insufficient antecedent basis for this limitation in the claim. The applicant had previously recited a "pliable base" but not a "posterior base".

5. Claims 15, 16, 28-33 and 45 also recite the limitation "the posterior base".

6. Claim 7 recites the limitation "the distal end lumen" in line 4. There is insufficient antecedent basis for this limitation in the claim.

7. Claims 7 and 45 recite the distal end of the respiratory tube comprising at least one lumen having a diameter that is smaller than the diameter of the distal end lumen. However, it is unclear as to how the distal end of the respiratory tube can include a lumen that is smaller than the distal lumen because claim 1 recites that the distal lumen terminates at the distal end. The claims do not recite the distal end having any

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additional lumens. Therefore, the claims are deemed indefinite and have not been under any prior art rejections.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. **Claims 1, 2, 8-14, 17, 20-26, 30, 31, 33, 35, 37, 39, 40, 43 and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,355,879 to Brain.**

(claims 1 and 33) Brain discloses a laryngeal mask comprising:

an inflatable positioning shield, the shield having an inflatable peripheral portion 18, a pliable base 13 (constructed from silicone; col. 2, lines 59-60), a shield recess (defined by element 31), a rear portion 30 formed between the pliable base and the peripheral portion (where respiratory tube connects), wherein the posterior base has a recessed front portion (the tip portion); and

a respiratory tube 11 having a proximal end lumen, a curved tubular body (Fig. 1), a distal end passing through and secured to the rear portion of the positioning shield (Fig. 4), the distal end terminating at a distal lumen located within the rear portion, the distal lumen passing through and secured to the rear portion of the positioning shield

such that tubes are capable of passing through the respiratory tube into the laryngeal opening (through aperture 14).

(claim 2) The respiratory tube and the position shield are pre-curved (Fig. 1).

(claim 8) The tubular body of the respiratory tube is of sufficient length to permit the proximal end to be displaced adjacent but external to the oral cavity (Fig. 1).

(claim 9) The proximal end lumen of the respiratory tube is adapted to attach to medical devices, such as a ventilator.

(claim 10) The peripheral portion of the inflatable positioning shields surrounds the laryngeal opening after inflation, which is the intended use of a laryngeal mask.

(claim 11) The inflatable positioning shield is generally ovoid in shape after inflation (Fig. 2).

(claim 12) The inflatable positioning is secured airtight to the exterior surface of the respiratory tube in socket 30.

(claim 13) The recessed front portion is in fluid communication with the respiratory tube. There is no structure to prevent the flow of air from the respiratory tube to the recessed front portion.

(claim 14) The positioning shield is of sufficient size to enclose the laryngeal opening.

(claim 17) The distal lumen defined in the socket **30** has the same cross-sectional shape as the respiratory tube.

(claim 20) The proximal end of the respiratory tube includes a tube adapter that provides a bigger diameter than the distal end of the respiratory tube.

(claims 21, 23 and 24) The distal lumen that terminates at the distal end of the respiratory tube is a circular lumen, which can have an upper portion and a lower portion, and which is still smaller than the diameter of the tube adapter at the proximal end. The distal lumen can be divided into asymmetrical halves so that the upper portion can have a diameter that is different from the lower portion.

(claim 22) The distal lumen is an opening, so it is inherently open upon assertion of pressure.

(claim 25) The recessed front portion is part of the mask assembly that is made of silicone, so it is sufficiently pliable to cup the patient's trachea.

(claim 26) The peripheral portion is wedge-shaped (Fig. 2A).

(claim 30) See the rejections to claims 1 and 23.

(claim 31) See the rejections to claims 1, 21 and 24.

(claim 35) See the rejection to claim 1.

(claim 37) The respiratory tube has a circular cross-sectional shape.

(claim 39) The distal lumen of the respiratory tube perforates the distal end of the respiratory tube.

(claim 40) The evacuation tube **51** is capable of providing alternate means of ventilation.

(claim 43) See the rejection to claim 23.

(claim 44) See the rejection to claim 21.

**10. Claims 34, 41-42 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,240,922 to Pagan.**

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(claim 34) Pagan teaches a laryngeal mask comprising horizontal runners **31-33** that is viewed as a means for elevating an epiglottis, which surrounds a portion of the perimeter of the lumen and does not obstruct the lumen. It is also noted that the Pagan reference qualify as a prior art because the structure of the horizontal rib is not present in any of the parent cases.

(claims 41-42) The horizontal runners is a means for inhibiting foreign matter.

***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action: .

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**13. Claims 3-6, 18, 19, 27 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brain ('879) in view of US 5,682,880 to Brain ('880).**

(claims 3-5) The '879 reference is silent with regards to the respiratory tube having an elliptical cross-section and made from a material with a low coefficient of friction to facilitate the delivery of an endotracheal tube. However, the '880 reference



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discloses a respiratory tube having an elliptical cross-section with an endotracheal tube located within (Fig. 2). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the respiratory tube of the '879 reference to that of the '880 reference because it allows an elliptical endotracheal tube to be used and inserted into the respiratory tube and laryngeal mask with little difficulty. The '880 reference teaches that the respiratory tube is made of silicone, which has a low coefficient of friction. The respiratory is also flexible (col. 2, line 67) and is therefore capable of deforming radially.

(claims 6, 18, 19 and 36) The modification to use a respiratory tube with an elliptical cross-section would also modify the distal lumen to have an elliptical cross-section in order to receive the respiratory tube.

(claim 27) See the rejections to claims 1 and 5. It is noted that the distal end of the respiratory tube is perforated as it includes a distal lumen.

**14. Claims 15, 16, 28, 29 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brain ('879) in view of US 6,240,922 to Pagan.**

(claims 15 and 16) Brain teaches all the limitations of the claims except for the recessed front comprising at least one support member adapted to stabilize the pliable base, wherein the at least one support member is at least one raised horizontal runner. However, Pagan teaches a similar laryngeal mask, wherein the mask includes a recessed front portion with horizontal runners **31-33**, which act to hold the epiglottis away from the tube opening. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the mask of Brain to include



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the ribs taught by Pagan because it would prevent the epiglottis from blocking the tube opening during insertion of the mask assembly. The modification to include the ribs would also inherently stabilize the pliable base.

(claim 28) See the rejections to claims 1, 16 and 21.

(claim 29) See the rejections to claims 1, 16, 21 and 22.

(claim 32) See the rejections to claims 1, 16, 21 and 24.

**15. Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brain ('879) in view of US4,995,388 to Brain ('388).**

The '879 reference teaches all the limitation of the claim, including a flexible respiratory tube, but is silent with regards to the materials used for the respiratory tube. However, the '388 reference teaches a similar laryngeal mask that uses a silicone based respiratory tube (col. 4, lines 28-29). Therefore, because these two flexible tubes were art-recognized equivalents at the time the invention was made, one of ordinary skill in the art would have found it obvious to substitute the flexible silicone rubber tube for the flexible tube of the '879 reference.

### ***Double Patenting***

16. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

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F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

**17. Claims 1-14, 16, 17, 27, 35, 36, 39, 41 and 42 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 5,937,860.** For double patenting to exist between the rejected claims and the patented claims, it must be determined that the rejected claims are not patentably distinct from the patented claims. In order to make this determination, it first must be determined whether there are any differences between the rejected claims and the recited patented claims and, if so, whether those differences render the claims patentably distinct.

Claim 1 recites a laryngeal mask comprising an inflatable positioning shield having a peripheral portion and a recessed front, and a flexible respiratory tube having a proximal lumen, a gently curved body, and a distal end..

It is clear that all the elements of claim 1 are to be found in claim 1 of the patent. The difference between claim 1 of the application and claim 1 of the patent lies in the fact that the patent claim includes additional elements and is thus much more specific. Thus the invention of claim 1 of the patent is in effect a "species" of the "generic" invention of claim 1 of the application. It has been held that the generic invention is "anticipated" by the "species". See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

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Since claim 1 of the application is anticipated by claim 1 of the patent, it is not patentably distinct.

As to claims 2-14, 16 and 17, see claim 2-16 of the patent, respectively.

As to claim 27, see claim 17 of the patent and the reasons set forth in the rejections to claim 1.

As to claim 35, see claim 1 of the patent.

As to claim 36, see claim 3 of the patent.

As to claim 39, see claim 7 of the patent.

As to claims 41 and 42, see claims 15 and 16 of the patent.

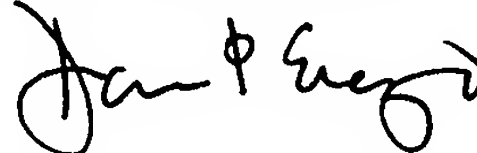
### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezzo whose telephone number is (571) 272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Darwin P. Erez  
Examiner  
Art Unit 3731

de